

APR 17 2007

**REMARKS**

In the non-final office action mailed January 22, 2007, claims 20-60 were pending and stand rejected. Claims 20, 36, 39, 48 and 55 have been amended in this response. Reconsideration of the present application as amended and including claims 20-60 in view of the remarks that follow is respectfully requested.

**Claim Rejections – 35 U.S.C. §103**

Claims 20-36, 39-41, 43-48 and 50-52 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,505,732 to Michelson (hereafter "the Michelson patent") in view of U.S. Patent No. 6,258,125 to Paul et al. (hereafter "the Paul patent"); claims 37, 42 and 49 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Michelson patent in view of the Paul patent in further view of U.S. Patent No. 5,766,252 to Henry et al. (hereafter "the Henry patent"); claims 53, 54 and 58-60 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Michelson patent in view of the Henry patent; and claims 55-57 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Michelson patent in view of the Henry patent in further view of the Paul patent. The Applicants note that the *Office Action Summary* indicates that claim 38 was rejected but that the "DETAILED ACTION" portion does not include any indication as to why claim 38 was rejected. However, considering that the subject matter of claim 38 is similar to that of claim independent claim 20, the Applicants are assuming it was rejected for the same reasons as claim 20.

It is well established that "[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." Manual of Patent Examining Procedure (MPEP) §2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Moreover, the suggestion/motivation to combine or modify under §103 needs to be specific. Where a "statement is of a type that gives

only general guidance and is not specific as to the particular form of the claimed invention and how to achieve it ... [s]uch a suggestion may make an approach 'obvious to try' but it does not make the invention obvious." *Ex parte Obukowicz*, 27 USPQ2d 1063, 1065 (U.S. Pat. and Trademark Off. Bd. of Pat. App. & Interferences 1993) (*citations omitted*).

Independent claim 20 has been amended to more clearly define the present invention and now recites, among other features, "... wherein at least one of said first and second distractor tips includes a first transition surface extending between a distal end surface and said first surface of said at least one distractor tip and a second transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane. . ." Support for the amendment to claim 20 may be found, for example, in the written description on page 36, lines 6-8 and in Figures 54-56.

As indicated above, to establish a proper obviousness rejection the combination of references must teach or suggest all the claim limitations. The Office Action indicates that the Michelson patent discloses all of the features of claim 20 except for at least one of the first and second distractor tips including first and second transition surfaces. However, the Office Action asserts the Paul patent discloses the claimed transition surfaces and suggests modifying the Michelson patent in view thereof. With respect to the Paul patent, it discloses implants configured for use during a posterior lumbar interbody fusion (PLIF) procedure. (See column 1, line 15 to column 2, line 7 and column 5, lines 37-53). With specific regard to implant 10, it includes an anterior side 26 with rounded edges 30, which as disclosed by the Paul patent, "enable implant 10 to slide between the end plates. . ." (See column 4, lines 16-19). However, contrary to the language of claim 20, the Paul patent does not teach or suggest that the rounded edges 30 have "a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim." Moreover, as those having skill in the art would appreciate, the procedure disclosed by the Paul patent teaches away from an implant having this feature. For example, it teaches that the anterior and lateral annulus remain intact after preparation of the disc space. (See column 5, lines 46-48). To the extent that any portion of the anterior annulus 112 extends posteriorly beyond the cortical rim into the disc space, it would prevent the implant 10

from being positioned against the cortical rim without potentially displacing the annulus 112 in the anterior direction. Such displacement would increase the likelihood of interference between the anterior annulus 112 and neighboring anatomical features, which, considering the permanent nature of the implant 10, is an undesirable effect. Furthermore, the Paul patent teaches that autogenous cancellous bone or a bone substitute should be placed in the anterior aspect of the disc space (see column 6, lines 6-9), which further indicates that the implant 10 is not positioned against the cortical rim. Accordingly, the Paul patent does not disclose, nor is there any teaching or suggestion, that the rounded edges 30 include "a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim." Moreover, even assuming only *arguendo* that the Paul patent discloses this feature, inasmuch as the implant 10 is implanted with the rounded edges 30 positioned anteriorly, it is clear that the rounded edges 30 do not have a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates as recited in claim 20.

Additionally or alternatively, the Applicants submit that those having skill in the art would not be motivated to modify the Michelson patent in view of the Paul patent as suggested. In support of the suggested modification, the Office Action indicates that it would "facilitate insertion of the device (column 4, lines 16-20)", as the Paul patent discloses in regard to the rounded edges 30. However, the Paul patent also discloses that the rounded edges 30 minimize the necessary distraction of the end plates. (See column 4, lines 19-20). Likewise, those having skill in the art would not be motivated to include the rounded edges 30 on the distractor tips of the Michelson patent since such a modification would minimize distraction of the end plates in contravention to the distractor tips' intended purpose, which is distraction.

Additional reasons also support the lack of suggestion or motivation to combine the references as suggested. For example, the cited portions of the Michelson patent teach distractor tips which are temporarily inserted into a disc space through an anterior approach while the Paul patent teaches implants which are permanently implanted in a disc space through a posterior approach. As those having skill in the art would appreciate, certain anatomical considerations must be given in regard to different implantation approaches and techniques. For example, the Michelson patent teaches side by side distracting which due to size restrictions is not practiced from the posterior approach taught by the Paul patent. Accordingly, there is no suggestion or

motivation for those having skill in the art to modify the anterior approach distractor tip of the Michelson patent in view of the posterior approach implant taught by Paul. Furthermore, those having skill in the art would not be motivated to look to the permanently implanted devices of the Paul patent to modify the temporarily implanted distractors of the Michelson patent considering the various distinctions therebetween. For example, due to their permanent nature, the implants of the Paul patent are inserted entirely within the disc space in view of various considerations, including eliminating interference with surrounding anatomical features and reducing potential expulsion from the disc space over time. To the contrary, inasmuch as the distractor tips of the Michelson patent are only temporarily inserted, the above considerations are absent. Instead, each of the distractor tips includes an increased diameter head 128 which engages with the anterior side of adjacent vertebral bodies and prohibits the distractor tip from being entirely inserted within the disc space. Accordingly, there is no suggestion or motivation for those having skill in the art to look to the permanently inserted implant of the Paul patent to modify the temporarily inserted distractor tip of the Michelson patent.

Therefore, for at least these reasons, claim 20 is submitted as patentable over the cited references and withdrawal of the rejection thereof is respectfully requested. Each of claims 21-38 depends from claim 20 or an intervening claim and is submitted as patentable for at least the reason supporting the patentability of claim 20. However, further reasons support the patentability of the claims depending from claim 20. For example, claim 23 recites that "said recessed area is configured to permit rotation of a surgical instrument positioned adjacent thereto." However, the Paul patent does not disclose that the channel 20, cited by the Office Action, is configured in this manner. Instead, it only teaches that the channel 20 is sized to receive a surgical instrument for implantation of the implant 10. Moreover, it is clear that the implant 10 does not include a convex surface along a medial side thereof as set forth by claim 25. Rather, as illustrated in any of Figures 1, 3 or 4 for example, the lateral side 18 is substantially linear without any convex surface. Claim 34 recites that the first distractor includes a projection which is positioned in a notch of the second distractor to prevent relative movement between the first and second distractors. However, this feature is not disclosed by either of the Michelson or Paul patents.

As indicated above, claim 39 was also rejected under 35 U.S.C. §103(a) as being unpatentable over the Michelson patent in view of the Paul patent. Independent claim 39 has also been amended and now recites, among other features, "... wherein at least one of said first and second distractor tips includes a first transition surface extending between a distal end surface of said at least one distractor tip and said first surface of said at least one distractor tip and a second transition surface extending between said distal end surface and said second surface of said at least one distractor tip, said first and second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates in a sagittal plane. . ."

Independent claim 39 is submitted as patentable over the cited references for at least the reasons set forth above in support of the patentability of claim 20. For example, neither of the references teaches or suggests a transition surface having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim located at a posterior region of vertebral endplates. Additionally or alternatively, there is no suggestion or motivation to modify the Michelson patent as suggested in the Office Action. Accordingly, withdrawal of the rejection of claim 39 and allowance of same are respectfully requested. Each of claims 40-45 depends directly from claim 39 and is submitted as patentable for at least the reasons supporting the patentability of claim 39.

Claim 46 also stands rejected under 35 U.S.C. §103(a) as being unpatentable over the Michelson patent in view of the Paul patent. Claim 46 recites, among other features, "... wherein at least one of said first and second distractor tips includes a lateral surface opposite the other of said first and second distractor tips when positioned therealong and a first transition surface extending between a distal end surface of said at least one distractor tip and said lateral surface, said first transition surface having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in an axial plane. . ."

The Office Action indicates that one having skill in the art would be motivated to modify the Michelson patent in view of the implants 70, 70' disclosed in Figure 9 of the Paul patent to arrive at the invention of claim 46. However, for reasons similar to those submitted above with respect to claim 20, claim 46 is also submitted as patentable over the combination of references. For example, the Paul patent does not disclose that any portion of the implants 70, 70' has "a

curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim" in an axial plane. Moreover, considering the Paul patent teaches that the lateral annulus 114 remains intact after preparation of the disc space, those having skill in the art would appreciate that it teaches away from requiring an implant having the claimed curvature. For example, to the extent that any portion of the lateral annulus 114 extends medially beyond the cortical rim into the disc space, it would prevent the implants 70, 70' from being positioned against the cortical rim without potentially displacing the annulus 114 in the lateral direction. Such displacement would increase the likelihood of interference between the lateral annulus 114 and neighboring anatomical features, which, considering the permanent nature of the implants 70, 70', is undesirable. Accordingly, the Paul patent does not disclose, nor is there any teaching or suggestion, that any portion of the implants 70, 70' includes "a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in an axial plane."

Additionally or alternatively, for the same reasons indicated above with respect to claim 20, there is no suggestion or motivation for those skilled in the art to make the suggested modifications to the Michelson patent. For at least these reasons, independent claim 46 is submitted as patentable over the cited references and withdrawal of the rejection and allowance thereof are respectfully requested. Each of claims 47-52 depends directly from base claim 46 and is submitted as patentable for at least these reasons as well. With respect to claim 48, it has been amended and now recites, among other features, "said second and third transition surfaces each having a second curvature generally corresponding to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a sagittal plane." As indicated above with respect to claim 20, the Paul patent does not disclose this feature.

As indicated above, claim 53 has been rejected under 35 U.S.C. §103(a) as being unpatentable over the Michelson patent in view of the Henry patent. Independent claim 53 is directed to a surgical assembly for distracting a spinal disc space and recites, among other features, "... wherein at least one of said first and second distractor tips includes a lateral surface opposite the other of said first and second distractor tips when positioned therealong and a first transition surface extending between said lateral surface and said first surface and a second transition surface extending between said lateral surface and said second surface, said first and

second transition surfaces each having a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in a coronal plane. . .” As will be discussed below, claim 53 is submitted as patentable over the cited references.

The Office Action indicates that the Michelson patent discloses all of the features of claim 53 except for the first and second transition surfaces which are instead taught by the Henry patent. With respect to the Henry patent, it discloses implants configured for use during a posterior lumbar interbody fusion (PLIF) procedure. (See Figures 7-14). With specific regard to the implant 20 cited in the Office Action, it includes sides 28 which have a convex arcuate surface contour. However, contrary to the language of claim 53, the Henry patent does not disclose that the sides 28 each have “a curvature shaped to generally correspond in shape to a curvature of an inner portion of a cortical rim of vertebral endplates in a coronal plane.” Furthermore, there is no teaching or suggestion that the sides 28 include the claimed curvature. Instead, the Henry patent teaches that the implant 20 is wedged “within the resilient tissue of the disc 68 to secure the prosthetic implant 20.” (See column 4, lines 51-53 and the illustrations of Figures 9 and 13). Accordingly, there is no reason why the sides 28 would include the claimed curvature and therefore the Henry patent fails to teach or suggest this feature as well. Consequently, the combination of references fails to teach or suggest all the claim limitations and a prima facie case of obviousness has not been established.

Additionally or alternatively, the Applicants submit that those having skill in the art would not be motivated to modify the Michelson patent in view of the Henry patent as suggested. For example, the cited portions of the Michelson patent teach distractor tips which are temporarily inserted into a disc space through an anterior approach while the Henry patent teaches implants which are permanently implanted in a disc space through a posterior approach. As indicate above, anatomical considerations must be given in regard to different implantation approaches and techniques. For example, the side by side distracting taught by the Michelson patent may not be practiced from the posterior approach taught by the Henry patent due to size restrictions as well. Accordingly, there is no suggestion or motivation for those having skill in the art to modify the anterior approach distractor tip of the Michelson patent in view of the posterior approach implant taught by Henry. Furthermore, those having skill in the art would not be motivated to look to the permanently implanted devices of the Henry patent to modify the

temporarily implanted distractors of the Michelson patent considering the various distinctions therebetween. For example, due to their permanent nature, the implants of the Henry patent are inserted entirely within the disc space in view of various considerations, including eliminating interference with surrounding anatomical features and reducing potential expulsion from the disc space over time. To the contrary, insomuch as the distractor tips of the Michelson patent are only temporarily inserted, the above considerations are absent. Instead, each of the distractor tips includes an increased diameter head 128 which engages with the anterior side of adjacent vertebral bodies and prohibits the distractor tip from being entirely inserted within the disc space. Accordingly, there is no suggestion or motivation for those having skill in the art to look to the permanently inserted implants of the Henry patent to modify the temporarily inserted distractor tips of the Michelson patent.

Therefore, claim 53 is submitted as patentable over the cited references for at least these reasons. Each of claims 54-60 depends from claim 53 or an intervening claim and is submitted as patentable for at least the reasons supporting the patentability of claim 53. Claim 55 was rejected as being unpatentable over the Michelson patent in view of the Henry patent in further view of the Paul patent. Claim 55 has been amended and now recites: "...said third and fourth transition surfaces each having a second curvature generally corresponding to a curvature of the inner portion of the cortical rim located at a posterior region of vertebral endplates in a sagittal plane." As indicated above, the Paul patent does not disclose this feature. Therefore, claim 55 is further submitted as patentable over the combination of references.



APR 17 2007

**CONCLUSION**

In view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance with pending claims 20-60. Reconsideration of the subject application as amended is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

By: Douglas A. Collier  
Douglas A. Collier  
Reg. No. 43,556  
Krieg DeVault LLP  
One Indiana Square, Suite 2800  
Indianapolis, Indiana 46204-2079  
(317) 238-6333 voice